

CONCLUSIONS The point estimates in the meta-analyses suggest that thrombus aspiration may prevent four deaths per thousand at the cost of two strokes per thousand. Although this may initially sound favorable for the procedure, the confidence interval for mortality is still wide enough to encompass no effect, while that of stroke is not. With mortality now so low in STEMI trials, very large numbers of patients are required to reliably identify a clinically important improvement. The task requires massive multi-center trials or strategies that minimize per-patient costs by using established outcome-reporting infrastructure to focus on mortality, and perhaps introduce “retrospective consent”.

CATEGORIES CORONARY: Thrombus / Thrombectomy and Embolic Protection

TCT-263

Relationship Between Therapeutic Effects on Infarct Size in Acute Myocardial Infarction and One-year Outcomes: Patient-Level Analysis of Randomized Clinical Trials

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BACKGROUND Several studies of acute myocardial infarction (MI) have documented the prognostic importance of early post-MI infarct size related to long-term outcomes such as mortality or heart failure (HF). However, whether a change in infarct size due to an intervention is related to the intervention's effect on outcomes has not been conclusively demonstrated. We used patient-level data from acute MI primary PCI trials to assess the relation between short-term effects on infarct size and longer-term effects on outcomes. We hypothesized that a therapy-induced change in infarct size would be related in direction and/or magnitude to the outcome effect of that therapy.

METHODS We combined patient-level data from 10 randomized clinical trials that tested various therapies for ST elevation MI (STEMI). Infarct size was assessed by sestamibi imaging in 3 trials and by cardiac magnetic resonance imaging in 7 trials, using standard techniques with analysis in core labs, and was expressed as a % of left ventricular (LV) mass. Each patient within a trial was assigned a variable to represent that study treatment's mean effect on infarct size based on whether the patient was in the treatment or placebo group. Cox proportional hazards models estimated the association of treatment-related infarct size to one-year adjudicated clinical outcomes of hospitalization for heart failure and all-cause mortality.

RESULTS The 10 trials included 2,458 patients, 24% women, 7% with prior MI. Infarct size was measured at a median of 5 days post-MI. Mean trial infarct size in the control groups in the 10 trials ranged from 12% - 35% of the LV, and from 12% - 40% among treatment groups. There was a significant relation of treatment effect on infarct size to treatment effect on one-year HF hospitalization (HR 0.83, 95% CI 0.75 to 0.93, $p < 0.001$). There was no significant relation between treatment effect on infarct size to treatment effect on one-year mortality (HR 1.04, 95% CI 0.94 to 1.15). The relation to HF hospitalization was stable in sensitivity analyses adjusting for time from MI to infarct size assessment, and for considering HF as the main outcome and death as a competing risk.

CONCLUSIONS This patient-level analysis of randomized placebo-controlled trials of multiple therapeutics for STEMI suggests that a treatment-induced effect on infarct size is related in direction and quantifiable magnitude to a treatment effect on HF hospitalizations. The data enable the consideration of incorporating infarct size assessment into novel trial analytic approaches as a surrogate endpoint to assess new therapeutics.

CATEGORIES CORONARY: Acute Myocardial Infarction

KEYWORDS Clinical Trial, Infarct size, Outcomes

TCT-264

14 Years' Experience in a Two-step Strategy for the Treatment of Acute ST-Segment Elevation Myocardial Infarction by Percutaneous Coronary Intervention Based on a Minimalist Immediate Mechanical Intervention with Deferred Stenting. A Single Centre Study

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BACKGROUND No reflow phenomenon is not uncommon in patients with acute ST-segment elevation myocardial infarction (STEMI) directly revascularized by PCI with immediate stenting (IS). We previously showed in a pilot study that a minimalist immediate mechanical intervention (MIMI), based on the use of guidewire or undersized balloons to avoid both large dissection and distal embolization, may be sufficient to restore flow in emergency in most of patients with acute STEMI and that recanalization may be sustained by optimized antithrombotic regimen allowing to postpone stenting in better conditions. MIMI also allows to schedule more appropriate medical or surgical alternative management when more suitable for the patient. We report in the present study our experience in MIMI approach over 14 years.

METHODS From April 2001 to May 2015, among 2074 primary PCI performed in our institution, 1591 were done for a TIMI 0 flow of the infarct-related artery (IRA) at admission coronary angiogram. The choice between IS and MIMI was done depending on presence of a large thrombus, complex lesion (bifurcation), indication for urgent or semi-urgent surgery, questionable significant stenosis underlying thrombus.

RESULTS IS was performed in 950 cases. The guidewire or the balloon failed to cross the lesion in 14 of the 1591 patients (0.9%). Among the remaining 627 cases in whom IS was not performed, once the infarct-related artery had been recanalized using MIMI, 483 cases underwent a two-step strategy. The final strategy was medical in 55 cases (10%), surgery in 170 (35%) and deferred stenting (DS) in 258 (55%) at a mean of 4 ± 4 days after initial PCI. IRA reocclusion before final strategy occurred in 1% in all cases with post-MIMI TIMI 3 flow and in 5 of the 17 cases (29%) with post-MIMI TIMI 2 flow. The rates of no-reflow and TIMI 3 flow after stenting in the DS group were 0% and 98.4%, respectively vs 1.8% and 91% in the IS group ($p < 0.001$). Distal embolization occurred in 1.8% of the IS and in 0.4% in the DS group ($= 0.19$). The total rate of TIMI flow < 3 and distal embolization after stenting was 11% in the IS group compared to 2% in the DS group ($p < 0.0001$).

CONCLUSIONS This study suggests that a two-step strategy for the treatment of acute STEMI by PCI based on a MIMI approach with deferred stenting is possible and seems to achieve better immediate angiographic results than immediate stenting. However, if a two-step strategy is applied, a TIMI 3 flow is mandatory after MIMI to avoid early reocclusion before the final strategy.

CATEGORIES CORONARY: Acute Myocardial Infarction

KEYWORDS Acute myocardial infarction, Angioplasty, Primary percutaneous coronary intervention

TCT-265

Impact of Platelet Count on Myocardial Infarct Size and Adverse Events in Anterior ST-Elevation Myocardial Infarction: Results from the INFUSE-AMI Trial

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BACKGROUND Platelets play a central role in ST-segment elevation myocardial infarction (STEMI) pathobiology and in the no-reflow